STATE OF WASHINGTON

DEPARTMENT OF SOCIAL AND HEALTH SERVICES

P.O. Box 45506, Olympia, Washington 98504-5506

September 9, 2005

Dear Interested Parties:

I am writing in response to your concerns about how DSHS, Health and Recovery Services Administration (HRSA) treats new medications that have not yet become part of the state's preferred drug list (PDL). HRSA, Labor and Industries (L&I), and the Health Care Authority (HCA) continue to work toward implementing an evidence-based preferred drug list that reflects the legislature's intent to ensure that patients receive the drugs they need while encouraging practitioners to use the PDL when it is appropriate for their patients.

The evidence-based preferred drug list (PDL): To implement the legislature's directive to create an evidence-based PDL, the agencies contracted with Oregon Health & Sciences University (OHSU) to produce evidence-based reviews of drug classes. These reviews serve as the basis for the state's Pharmacy & Therapeutics (P&T) Committee's recommendations to the agencies as to what specific drugs should be included on the PDL.

From time to time, a particular drug is not included in the OHSU/P&T Committee review because it did not come onto the market in time to be included in the review. Because these drugs have not been through the evidence-based review process, the agencies treat them as though they are not part of the PDL, even if the class to which they belong is included on the PDL. The agencies treat these drugs like any other drug that has not been through the review process. For HRSA and L&I this may include subjecting them to prior authorization requirements for safety reasons.

Because these drugs are not part of the PDL, the therapeutic interchange, endorsing status, and dispense as written provisions of SB 6088 do not apply. Currently, these updated reviews are scheduled at least annually, and may be conducted sooner in specific circumstances. In the interim, the agencies treat them according to their independent pharmacy benefit structures until an updated review of the drug class can be completed by OHSU and the P&T Committee. For HRSA, our policy is set forth in WAC 388-530-

1290 and we have followed a practice that requires a provider to document that the client has tried and failed or is intolerant to a preferred agent before receiving a non-preferred agent. This policy has been in place since the inception of the HRSA PDL program in 2002.

Continuation of therapy: To protect patients who are undergoing a course of therapy on certain drugs, SB 6088 contains an exemption to the therapeutic interchange provisions. When a prescription is for the continuation of therapy with the same drug (including renewals of a previous prescription or an adjustment in dosage) within the antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug classes, a patient will receive the specific drug without therapeutic interchange regardless whether the practitioner has endorsed the PDL. See RCW 69.41.190 and WAC 388-530-1290 (5).

Refills for exempted classes: Once a drug class is reviewed by OSHU and the P&T Committee, the "refill" exemptions apply to all clients currently on any exempted drug.

"New starts" of therapy: When a prescription is for a "new start" for a new course of therapy, the therapeutic interchange and dispense as written provisions of SB 6088 will apply for practitioners who have endorsed the PDL. Non-endorsing practitioners can prescribe non-PDL drugs, but for HRSA and L&I they may have to satisfy prior authorization requirements as discussed above.

New starts of therapy for drugs that are not on the PDL because they were not included in the OHSU/P&T Committee review: As explained above, these drugs are not considered part of the PDL, so the agencies treat them according to their independent pharmacy benefit structures like all other drugs that have not been through the evidence-based review process. For new starts of non-PDL drugs, HRSA and L&I may require all practitioners to satisfy prior authorization requirements before the drugs are dispensed. WAC 388-530-1250 and 1200 enables HRSA to use prior authorization in cases where there is concern about a drug's safety, high cost with low cost alternatives, potential for clinical misuse, and narrow therapeutic indications.

It is important to note that among the classes of drugs singled out in the "refill" exemptions, only second generation antidepressants are included on the PDL currently. In fact, under the current review schedule, the only other exempt drug classes that will be included on the PDL are the atypical antipsychotic and immunosuppressive drug classes. Among the antidepressant medications included on the PDL, only one drug was not on the market in time to be included in the OHSU/P&T Committee review: Cymbalta.

As a result, while refill prescriptions for continuation of therapy for Cymbalta will be filled as written, prescriptions for new starts of therapy with Cymbalta will only be filled by HRSA and L&I after the practitioner satisfies certain prior authorization criteria. These criteria include having tried and failed two of the preferred second generation antidepressant drugs, or intolerant to preferred agents at appropriate dose and duration or clinical rationale for prescribing a more expensive equally effective non-preferred drug. This criteria stems from discussions with the Mental Health Work Group (see below) that assisted HRSA in determining that failure of two of the preferred second generation antidepressant drugs should be tried at an appropriate dose and duration before escalating to multiple antidepressant drugs. Because the PDL class for antidepressant drugs contain many preferred options, HRSA thought this an acceptable threshold for non-preferred and non-PDL drugs in this class. Because Cymbalta is not currently part of the PDL, this requirement applies to all new starts for Cymbalta, regardless of a practitioner's endorsing status.

I want to emphasize that this prior authorization requirement for new starts of Cymbalta is unique because it was not included in the OHSU/P&T Committee review. On the other hand, Cymbalta like all other second generation anti-depressant drugs will be prescribed as written for continuation of therapy. Cymbalta was included in the most recent updated OHSU review of second generation anti-depressant drugs and will be part of the P&T Committee's review in March 2006.

Development of prior authorization criteria for second generation anti-depressants apply to non-endorsing practitioners, and to all practitioners with regard to Cymbalta regardless of endorsing status for the reasons stated above.

Since December 2004, HRSA and L&I have been meeting bi-monthly with a broad workgroup of mental health stakeholders to address concerns very similar to those expressed in your letter.

The Mental Health Work Group: In particular the workgroup tried to address the issue of multiple physicians prescribing multiple anti-depressants to a single patient, which poses significant concerns about patient safety and effective use of resources. Initial research showed there were 4,200 HRSA clients on 2, 3 or 4 anti-depressants at once, often without any evidence of enhanced benefit. In addition a survey of the top 700 physicians with clients on multiple anti-depressants suggested that roughly one-in-five of the surveyed physicians were unaware of the multiple dosing and nearly half (46%) stated that they would consider discontinuation of the duplicate anti-depressant medications. As a result, HRSA and L&I developed a set of rules around prescribing multiple antidepressants.

The mental health stakeholders' workgroup agreed that a patient must have tried and failed two preferred anti-depressants (for appropriate dose and duration) before prescribing multiple anti-depressant medications. This was also based in part on the OSHU/P&T Committee review conclusion that all anti-depressants were equally safe, effective and that there were no studies to indicate any special population would benefit from one generic or brand over another. The P&T Committee did recommend that there should be no therapeutic interchange for second generation anti-depressants because of the potential side effects noted for the class.

Significantly, the providers agreed with the agency's proposed prior authorization criteria for new drugs like Cymbalta that are not part of the PDL. The agencies also worked with the Department of Corrections to assist those patients in maintaining their mental health drugs once released from jail and onto Medicaid. Unfortunately, the pharmaceutical companies and some advocates remain opposed to any restrictions on these drugs.

"Tried and Failed" Criteria: I want to emphasize that the "tried and failed" prior authorization criteria being discussed currently applies to both HRSA and L&I patients for the second generation anti-depressants. "Tried and Failed" or an appropriate clinical rationale has been used from the beginning of the PDL as a prior authorization tool when non-endorsing providers request a non-preferred drug that is more expensive yet equally effective to the preferred drugs. Appropriate prior authorization criteria for other drugs that are subject to the refill exemptions of SB 6088 that may come onto the PDL in the future will be developed based on the result of an evidence-based review and stakeholder feedback.

I hope this information addresses your concerns. The agencies continue to work to develop policies and rules that reflect the legislative intent of the prescription drug program created by SB 6088. If I can provide you with additional information, please feel free to contact me directly at (360) 725-1612.

Sincerely,

Jeffery Thompson, MD MPH
Chief Medical Officer